

8/16/02

510(k) SUMMARY

**CureLight's ClearLight Phototherapy Device
(K013623) 1/3**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

CureLight Ltd.
2 Ha'ilan Street
Northern Industrial Zone, POB 247
Or Akiva 30600, Israel.

Phone: +972 (52) 691764
Facsimile: +972 (4) 8374897

Contact Person: Dr. Yoram Harth

Date Prepared: **August 7, 2002**

Name of Device and Name/Address of Sponsor

ClearLight Phototherapy Device, Model CL 420

CureLight Ltd.
2 Ha'ilan Street
Northern Industrial Zone, POB 247
Or Akiva 30600, Israel

Common or Usual Name

Light Therapy Device

Classification Name

Ultraviolet Dermatological Light

Predicate Devices

Avex Industries, Inc.'s Phototherapeutix
National Biological Corporation's Derma-Wand
PhotoMedex, Inc.'s XTrac Excimer Laser System, Model AL 7000
Respironics, Inc.'s Wallaby 3 Phototherapy System

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Intended Use / Indications for Use

The ClearLight Phototherapy System is intended to provide phototherapeutic light to the body. The ClearLight is generally indicated to treat dermatological conditions. The ClearLight is specifically indicated to treat moderate inflammatory acne vulgaris.

Technological Characteristics

The ClearLight Therapy System is a high intensity lamp intended for the therapy of dermatological disorders such as acne vulgaris by emitting visible light in the violet-blue range with fluency of light ranging between 50-200 mW/cm². The system includes a spectral band light source with spectral emittance concentrated in the violet/blue spectral band and an optical system for controlling spectra and beam parameters of the light source. It also includes a mechanical fixture for holding the light source at an adjustable distance and direction related to the skin treatment area, an electronic unit to control the duration, and power of the emitted radiation and to capture and store patient data via a touch screen (*i.e.*, control console), and a camera for capturing digital images.

Performance Data

The preclinical testing includes Electrical Safety and EMC testing, including the requirements of IEC 60601-1 “Medical Electrical Equipment Part 1 - General Requirements for Safety” and was tested in accordance to Medical Directive 93/42/EEC – EN 55011: 1998 + A1(99), Class A and IEC 60601-1-2 “Collateral Standard: Medical Electrical Equipment Electromagnetic Compatibility - Requirements and Tests.” ANSI/ESNA RP-27 1-96 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements ANSI/ESNA RP-27.3-96 Recommended Practice for Photobiological Safety for Lamps – Risk Group Classification Labeling.

In vitro testing demonstrated that exposure to high intensity narrow band light induced eradication of *p. acnes* by endogenic porphyrins.

Clinical data from the trial of the ClearLight device for the treatment of dermatological conditions supports substantial equivalence and demonstrates that the ClearLight device is safe and effective for the treatment of acne vulgaris.

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Substantial Equivalence

CureLight's ClearLight is substantially equivalent to other legally marketed Ultraviolet Dermatological Light devices. The ClearLight has the same intended use and general indications for use, and similar principles of operation and technological characteristics as the previously cleared predicate Avex Industries Ltd.'s Phototherapeutix devices; National Biological Corporation's Derma-Wand; PhotoMedex, Inc.'s XTrac Excimer Laser System, Model AL 7000; and Respironics Inc.'s Wallaby 3 Phototherapy System. In addition, the ClearLight's specific indication for use is subsumed within the general indications for use and encompassed by the specific indications for use of its predicate devices.

The ClearLight and its predicate devices are all light devices that are used to treat dermatological conditions by exposing the surface of the skin to light at precise wavelengths. Although there are differences in the technological characteristics of the ClearLight and its predicate devices, those differences do not raise new questions of safety or efficacy. Thus, the ClearLight is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2002

Curelight, LTD
c/o Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K013623

Trade/Device Name: Clearlight Phototherapy System, Model CL 420

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: May 23, 2002

Received: May 23, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

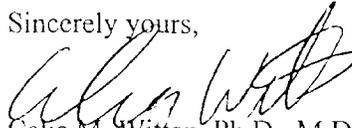
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Mr. Jonathan S. Kahan

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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Indications for Use Form

510(k) Number (if known): K013623

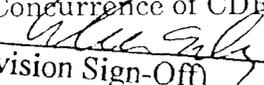
Device Name: ClearLight Phototherapy Device

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013623

Prescription Use
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)